UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO.: 05-CV-10241(MLW)

JULIE DELANEY and,
WILLIAM P. DELANEY,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

AFFIDAVIT OF AARON M. LEVINE, ESQ.
REGARDING AUTHENTICATION OF DOCUMENTS

I, Aaron M. Levine, declare under penalty of perjury that the following is true and correct:

1. Attached as Appendix 1 is a true copy of the Affidavit of Harold B. Sparr, R.Ph., M.S. dated September 20, 2006.

2. Attached as Appendix 2 is a true copy of the Report of Hannelore Vanderschmidt, Ph. D., dated August 26, 2004, and accompanying August 13, 2004 document.

3. Attached as Appendix 3 is a true copy of the Affidavit of Aaron M. Levine, Esq., dated November 29, 2006.

4. Attached as Appendix 4 is a true copy of the Expert's Report (Statement) of Harold B. Sparr, R. Ph., M.S., dated October 12, 2004.

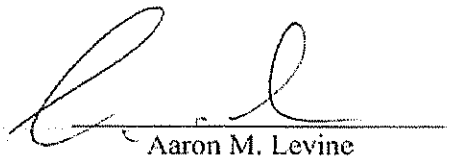
5. Attached as Appendix 5 is a true copy of A Phase II Study of a Combination of Pemetrexed and Gemcitabin in Patients with Metastic Breast Cancer: an NCCTG Study, available at http://www.lillytrials.com/results_filed/alimta/alimta_summary_2245.pdf.

6. Attached as Appendix 6 is a true copy of selected pages from the Deposition of George W. Price, July 29, 1983.

7. Attached as Appendix 7 is a true copy of selected pages from the Deposition of Harold B. Sparr, R. Ph., M.S., December 7, 2004.

8. Attached as Appendix 8 is a true copy of the Eli Lilly Wholesaler Agreement in effect in 1969 and 1970, as supplied by Defendant in response to discovery.

I declare under penalty of perjury that the foregoing is true and correct.



Aaron M. Levine

Dated: November 29, 2006

Appendix 1

Affidavit of Harold B. Sparr, R. Ph., M.S.

STATEMENT OF HAROLD SPARR, R.PH.

Harold B. Sparr declares under penalty of perjury that the following is true and correct:

1. I am a registered and licensed pharmacist in Massachusetts, New York, and California having graduated in ~~1951~~ 1955 (1953) from the Massachusetts College of Pharmacy. I have continuously and exclusively engaged in pharmacy from 1944 to the present.

2. I was the President of the Massachusetts Board of Registration in Pharmacy as well as the President of the Massachusetts College of Pharmacy Alumni Association, and as such am personally familiar with registered pharmacists in the Boston region, as well as the actual practice of pharmacy and retail pharmaceutical catalogues.

3. From the year 1944 to the present, I have worked at the following local Boston pharmacies:

a. Sparr's Drug Store, Inc. on 635 Huntington Avenue, Boston, MA (1944-1969);

b. Ivy Drug on Park Drive, Boston, MA (1955);

c. Jacobson's Pharmacy on Harvard Street, Boston (Dorchester), MA (1955-1956);

d. Robert's Pharmacy on 360 Trapelo Road, Belmont, MA (1969-1976);

4. I was a member of Boston Association of Retail Pharmacists (now called Massachusetts Independent Pharmacists Association) from 1955 to the present. In have had the opportunity to meet with, work with, and discuss the practice of pharmacy with hundreds of pharmacists in Boston, including Hingham, over the last fifty years.

5. I am familiar with those pharmaceuticals commonly used for the care and treatment of pregnant women in the late 1960's and early 1970's in the Boston area, including Hingham. I am also familiar with the pharmacy literature in the marketing of drugs in the 1960's and 1970's.

6. I am familiar with the Red and Blue Books and those publications' listings of many diethylstilbestrol (DES) manufacturers besides Eli Lilly in the 1960's and 1970's. However, while the Red and Blue Books may represent all the medications in the world, they have no relevance to the Boston areas as Lilly virtually owned that DES market in the 1960's and 1970's.

7. I am familiar with the practice of stocking and dispensing of DES in the 1960's and 1970's in Boston. In the 1960's and 1970's, generics were not popular and were disfavored in the trade sine they did not have the quality control of the major brands. Because Lilly was top quality, the Lilly DES drug was inexpensive, and could be ordered from a Lilly wholesalet on bottle at a time, the drugstores in Boston/Hingham stocked Lilly's DES exclusively.

8. Based upon my practice, experience, and observations of the practice of pharmacy in Hingham in the 1960's and 1970's, if a woman was dispensed DES/Stilbestrol as a white, round, cross-scored tablet in 1969-1970, she would have received Lilly's Diethylstilbestrol, as that was the only popular brand at that time in pill form in that place and no other brand fitting this description was available in Boston/Hingham at that time.

9. Squibb may have made a DES product in the area, but their DES pill does not match the mother's description of a white, cross-scored tablet without any other markings or writing on it. Also, Squibb's DES pill was called Stilbetin and if a mother's

prescription was written as Stilbestrol without a brand name specified, she would have received a Lilly product based on the wholesaler agreement, Lilly's exclusivity, and it was illegal at that time to replace one drug for another.

9. The import and design of the Red and Blue Books as it pertains to DES reflects a picture of the myriad and numerous regional generic bottlers of this chemical in the various cities and localities in America representing fifty different states and over a 100 different cities.

10. The Red and Blue Books do not represent nor were they designed to represent the availability of DES in the Boston market nor the manufacturer of the drug as it's only distributor.

11. The great number or the great majority of the DES companies listed were not manufactures of DES but only repackagers in local limited markets. That is, a pharmacists would repackage DES under his own label and sell it as a generic to pharmacists in this area. Of the brands listed, only a few were national pharmaceutical distributors, i.e., Lilly Squibb, Merck, Upjohn, Pfizer. The others were not national distributors and were not in Boston Massachusetts. 90% of the names listed under the Red and Blue Books are local generic repackagers of DES. Lilly dominated the DES market in those days.

I declare under the penalty of perjury that the foregoing is true and correct based on my personal knowledge.

Harold B. Sparr

Harold B. Sparr, R.PH.

Witness:

Diane G. Sparr

Address 310 Nahanton St. Newton, Ma. 02459

Dated: Sept 20, 2006

Appendix 2

Report of Hannelore Vanderschmidt, Ph. D.

Boston University

Center for Educational Development in Health
53 Bay State Road
Boston, Massachusetts 02215
617/353-4528
Fax: 617/353-7417
E-mail: *asegall@bu.edu*
hvanders@bu.edu

April 13, 2004

To whom it may concern

I agree to analyze, aggregate and summarize data from the pharmacist's survey regarding dispensing of Dyethylstilbestrol (DES) in the 1960's. Three hundred surveys are being sent out to Massachusetts' pharmacists who practiced in the 1960s. Remedy Pharmacy When surveys are returned, Management Services, Inc will send the completed surveys to me for analysis.

I will summarize each respondent's survey as follows:

- Name and address of pharmacist
- Pharmacy school attended
- When licensed to practice pharmacy in Massachusetts
- Name of pharmacy where respondent practiced
- Location of pharmacy (city or town)
- Brand or brands of Diethylstilbestrol (DES) ordinarily or customarily dispensed in the 5mg or 25mg size (pregnancy sizes)

For this service I will charge $800/day for four or five 5 days or $4,000 maximum. I will write a report on the findings and sign my name to the report.

Hannelore Vanderschmidt

Hannelore Vanderschmidt, PhD
Co-Director

Boston University

Center for Educational Development in Health
53 Bay State Road
Boston, Massachusetts 02215
617/353-4528
Fax: 617/353-7417
E-mail: *asegall@bu.edu*
hvanders@bu.edu

August 26, 2004
Mr. Harold Sparr, R.Ph., D.Ph., M.S,
P.O .Box 66
Otis, Massachusetts 01253
Dear Harold:

You have asked that I enter and analyze the responses to a questionnaire survey seeking to determine scientifically the market share in Massachusetts of the prescription drug Diethylstilbestrol (DES 5 & 25_{mg}), in the state in the 1960's. This assignment was further detailed in a letter from Aaron M. Levine to you dated May 5, 2004 (see Attachment 4). As a practicing pharmacist of forty-five years and the former president of the Massachusetts Board of Registration in Pharmacy you have advised me that in the fifteen years between 1955 and 1970 the market for this drug remained relatively stable, although the popularity of the drug slowly decreased.

Because we are attempting to determine market shares forty years later, when so many of the pharmacists who were practicing then may have moved, retired or died, a target population of those pharmacists who were practicing in the period 1963 to 1967 was determined to the be the most reasonable population that would be both available and knowledgeable at the same time typical and timely as to this query.

I reviewed the attached questionnaire and made several suggestions, which were incorporated. (See Attachment 1). Although I was not responsible for the sample or mailing, the methods used seem scientifically valid.

I consulted and considered the following document, after approving this study design: Lilly's experts proposed testimony of market share, (Attachment 5).

I met personally with you and Peter Steere to review their familiarity and insights into the dynamics and chronology of this market and to discuss some of the challenging issues we were facing:

a. How could we insure that the memories of the target group were reliable?
b. What number of returns would constitute as sufficient sampling?
c. What were the variables in the twelve-year period under study and how did this impact on the years selected?
d. What were the prescribing habits of various physicians prescribing this drug, i.e. how was the drug prescribed?
e. What were the indications for these prescriptions?

My responsibility with respect to the survey is outlined in my letter of agreement of April 13, 2004 (Attachment 6) in broad terms, I agreed to analyze, aggregate and summarize data from the pharmacist's survey regarding dispensing of Stilbestrol/Diethylstilbestrol (DES) in the 1960's.

Overview

A one page 11-item survey was sent to 370 currently licensed pharmacists who were originally licensed 1/1/63—6/30/67. (See Attachment 1) I received 159 responses of which 6 were duplicates. My analysis is based on the 153 unduplicated responses, a 41.4% return rate). Of these 153 responses 79 practiced in Massachusetts at some time from 1963 to 1967 (question 5) in a pharmacy which stocked DES in the pregnancy dosages (question 8). Of these 79 respondents 71 (89.9%) volunteered Lilly as the most likely brand to be dispensed (question 9), 2 (2.5%) volunteered Lilly along with other brands, 5 (6.3%) could not remember, and 1 (1.2%) volunteered a different brand (Upjohn).

Thirteen cases initially eliminated from consideration were reinstated in the follow up process.

To test statistical significance my null hypothesis is that pharmacies are as likely to dispense non Lilly DES as Lilly DES. Using the nomenclature of Ted Colton *Statistics in Medicine* (Little Brown, NY, 1974, p159) assume 0.05 is a small enough chance to reject the null hypothesis. The Lilly response $p=0.899$ and $\pi=0.5$. The critical ratio $z_c=6.99$. Using a two-tailed normal distribution $P<0.003$. The null hypothesis is rejected. In other words, the observed percentage of Lilly preference is very unlikely to come about by chance.

Analysis Process

The survey instrument is provided as Attachment 1. The instrument contains 9 open-ended questions and 2 close-ended questions. Data from each form were transcribed to a computer file using a specially designed program. After removal of duplicates the open ended responses were reorganized on a question-by-question basis using a second specially designed program. The result is provided as Attachment 2. The close-ended questions were read into SPSS statistical software. Frequency counts and a cross tabulation are provided as Attachment 3.

Questions 1-4

This personal address information is useful should follow up be required to clarify a response. These responses are bundled in the Section One of Attachment 2.

Question 5

The response identifies respondents who were retail pharmacists in Massachusetts either in 1965 or in the period 1963 to 1967, depending on which questionnaire the respondent

received. Of 153 unduplicated responses, 100 answered this question "yes", 66.2% of those who answered the question. See attachment 3.

This question was originally asked "During the period 1965 ...". Later questionnaires modified the date to "1963-1967". The follow up process contacted the respondents who had received the first questionnaire and who did not answer "yes". Thirteen provided new responses that are included in the survey rather than their original responses.

Questions 6 and 7

The response to this question identifies the name and location of the pharmacy in which the respondent practiced if the respondent answered question 5 "yes". The responses are in Section Two of Attachment 2. They represent locations widely scattered across the commonwealth.

Question 8

The response identifies respondents whose pharmacies stocked and dispensed DES in the pregnancy dosage during the 60's. Of 153 unduplicated responses, 89 (58.2%) answered this question "yes", 78.8% of those who answered the question. See attachment 3.

Question 9

This key question asks the respondent what brand of DES was most likely dispensed if the prescription did not name a brand. The question is open ended, providing no prompts. Only the 79 respondents who answered "yes" to both questions 5 and 8 qualified for analysis. Of the 79, 71 volunteered "Lilly" as reported above. To obtain this result Section Three of Attachment 2 containing the responses to question 9 is used. A listing of responses to questions 5 and 8 is used to identify the qualified group and the number of "Lilly" and other kinds of response are tabulated by inspection.

Question 10

This question provides space for respondent comment. Most respondents did not comment; see Section Four of Attachment 2. A few comments relevant to the survey:

- I do remember seeing DES by Brewer & Co. and also Parke-Davis because I worked in prescription department from 1959 until became registered in 1965 but by that time I believe the DES we used was Lilly.
- I only recall the Lilly brand at that time.
- Lilly was the #1 supplier of generics then.
- Squibb was also used. I recall 5g. tabs and am pretty sure we had 25g.
- Extremely frequently prescribed by many physicians to many women or all ages.
- I believe that we only stocked Lilly's brand but I could be mistaken. That was a long time ago!

Question 11

This question solicits the name of the wholesaler. Responses are provided in Section Five of Attachment 2. Among those frequently cited, in order of frequency of citation:

Gilman, James W. Daly, McKesson, Mass Wholesale, United Consumers, New England Wholesale.

Conclusions

My conclusions are as follows:

1. The survey is trustworthy and based on a well-grounded sampling, considering the past time of the event we are considering.
2. Hearsay and memory risks were satisfactorily minimized.
3. The numbers of possible responders was properly surveyed to obtain a representative sample.
4. The questionnaire contained clear, precise and non-leading questions, which were answered appropriately consistent with the sources of information.
5. The responders had no knowledge of the litigation nor could they have been influenced or sympathetic to any individual or company.
6. The mailings, return receipts and collating protected the security and impartiality of the survey.
7. My statistical analysis was in accordance with accepted and standard epidemiological procedures.
8. The study and its results meet or surpass the assignment I undertook as contained in a letter to you from an attorney who I understand represents DES daughters seeking compensation from the manufacturer. (See Attachment 4). However, neither this attorney, nor anyone else engaged in such litigation nor any of the claimants have played any role in the design or conduct of this survey or my conclusions.
9. This study is adequately free from any bias that could invalidate the results.
10. The Lilly experts' opinions (Attachment 5) do not focus on the State of Massachusetts or the time period, and are therefore invalid in answering the pertinent questions.

Based on the foregoing analysis I conclude to a reasonable degree of statistical certainty and within reasonable principles of sample surveying that the Lilly brand would have been dispensed in 90 out of 100 instances in response to prescriptions for DES that did not designate a brand within the Commonwealth of Massachusetts between the years 1963 to 1967. The error in this rate is ±6. This conclusion can be extended to other years in so much as dispensing habits did not change.

Sincerely,

Hannelore Vanderschmidt

Hannelore Vanderschmidt, PhD, Ed.M
Co-Director, Center for Educational Development in Health
Adjunct Associate Professor of Public Health, Boston University

Appendix 3

Affidavit of Aaron M. Levine, Esq.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JULIE DELANEY and WILLIAM P. DELANEY Plaintiffs, v. ELI LILLY AND COMPANY, Defendant.	)	Civil Action No. 05-CV-10241 (MLW)

AFFIDAVIT OF AARON M. LEVINE, ESQ.
REGARDING IDENTIFICATION

I, Aaron M. Levine, hereby declare:

1. I am the attorney for Plaintiffs Julie Delaney and William P. Delaney in this action. I am duly admitted to practice in the District of Columbia. I am fully familiar with the facts and circumstances of this case.

2. I have been engaged in DES litigation since the early 1980s.

3. I was the chairman of the DES litigation group of the Association of Trial Lawyers of America and served for most of the committee's life in that position. Affiant coordinated nationwide DES litigation and maintained contact with dozens of lawyers throughout the country who were dealing with DES litigation. I coordinated, served as clearinghouse, wrote newsletters and generally assisted in the national litigation to obtain compensation for DES daughters.

4. Affiant has published in articles on DES in legal and medical journals.

5. Affiant has personal knowledge of the legal defenses of DES manufacturers in at least 400 lawsuits. Through personal knowledge and conversations with other lawyers, Affiant has knowledge of 1,000 other DES cases.

6. The policy of my office has been to exercise transparency and provide DES manufactures, including Eli Lilly, with new developments in identification evidence during discovery.

7. In 2004, Affiant met with Mr. Harold Sparr, R. Ph. from The Massachusetts Board of Registration in Pharmacy, Mr. Peter Steere from Remedy Pharmacy Management Services, and Dr. Hannelore Vanderschmidt from Boston University, Center for Educational Development in Health to discuss the survey criteria in accordance with the Reference Guide on Survey Research", Reference Manual on Scientific Evidence, 2d ed., (Fern M. Smith ed., Federal Judicial Center 2000, pp. 229-271).

8. Dr. Vanderschmidt was able to define the survey objective, isolate and meet various challenges to the survey's validity, and determine the proper questions to be used on the questionnaire, as well as evaluate the survey sampling and administration process. She designed or approved all aspects of the questionnaire, data collection and correlation.

10. I merely memorialized the results and criteria promulgated at the meeting in the letter attached as Defendant's Exhibit 2.

11. Dr. Vanderschmidt then worked directly and exclusively with Mr. Harold Sparr and Mr. Steere, who had addresses and contacts in order to deliver and administer the survey to pharmacists. I was uninvolved in that process.

12. Dr. Vanderschmidt compiled and analyzed the survey results. I was uninvolved in that process.

13. Frequently, identification evidence points to non-Lilly defendants. In those cases, we would pursue the non-Lilly DES manufacturer of course.

14. Often, the identification evidence is so deficient that the cases are dismissed or rejected if the plaintiff cannot resort to market share liability. For example, if the mother of the plaintiff is dead or cannot remember what pill she took, and if there are no pharmacy records or live pharmacists.

15. In over 25 years of practice, we have sued a variety of DES manufacturers. Lilly, from what the numerous cases filed reflect, is in no way prejudiced or "targeted" by the Affiant.

16. However, it is also been our experience in the hundreds of DES cases in which we have been involved that the mother identifies the Lilly pills, 9 times out of 10. This ratio coincides exactly with the results of the scientific surveys we have conducted to determine the shares of the DES markets.

I declare under the penalty of perjury that the foregoing is true and correct.

Aaron M. Levine

Dated: November 29, 2006

Appendix 4

Expert's Report of Harold B. Sparr, R. Ph., M.S.

HAROLD B. SPARR, R.PH., D.PH., M.S.
210 NAHANTON STREET, UNIT 121
NEWTON, MA 02459
TELEPHONE: (617)969-5322

October 12, 2004

Aaron M. Levine, Esq.
Aaron M. Levine & Associates
1320 19th Street, N.W., 5th Floor
Washington, DC 20036

Dear Mr. Levine:

In accordance with your request of May 4, 2004, I have embarked upon a study, over the last four months, to determine the extent of the share of the pregnancy size (5_{mg} & 25_{mg}) DES Market (Stilbestrol - - Diethylstilbestrol) dispensed in the drug stores, in the Commonwealth of Massachusetts, for the 16 year period centered in 1965, i.e., 1955 to 1971. The six research areas which provide the basis of my opinion are:

1. My personal experience as a retail practicing pharmacist dispensing DES and teacher of pharmacy in Massachusetts over the last forty-nine years, including my experience as president of the Massachusetts Board of Registration in Pharmacy and my presidency of the Massachusetts College of Pharmacy Alumni Association.

2. Personal conversations, research and investigations, wherein I have contacted hundreds of Massachusetts pharmacists who were practicing retail pharmacy during the period of time under investigation.

3. A review of approximately 200 sworn, randomly collected Statements obtained by your office and by me over the last few years, of the recollection of over 200 retail Massachusetts pharmacists who were practicing in the period under review, including the deposition testimony and sworn statements of a wholesale pharmacist and discussions with wholesalers, as well as the dozens of actual prescriptions for DES we were able to find.

4. A literature search of the pertinent pharmacy and retail pharmaceutical literature covering the period under examination; and

5. A study employing standard survey and accepted academic bio-statistical analysis conforming to proper questionnaire, reporting and analysis practices, with the assistance of professional survey personnel.

6. A review of the Massachusetts retail drug store practices and DES marketing environment over the period 1954 to 1971, to determine year to year consistency, in order to determine if the practices were stable during the period under review, statewide, including:

   a. Economic factors;
   b. Social and cultural factors;
   c. Competitive factors;
   d. Technological change;
   e. Government and legal factors;
   f. Communication within the retail pharmacy industry;
   g. Disease incidences;
   h. Distribution of goods and services;
   i. Demographic factors;
   j. Physician prescribing habits;
   k. Wholesaler and manufacturer services, distribution, support and literature;
   l. Pharmacist education;
   m. Packaging and delivery of pharmaceuticals;
   n. Year to year innovation;
   o. Medical indications;
   p. Marketing and sales practice and demand;
   q. Deletion and addition to drug popularity;
   r. Product life cycle and shelf life;
   s. Prescriber motivation and prescribing habits;
   t. New drug promotion – old drug withdrawal;
   u. Sources of information to the retail pharmacist;
   v. Pharmaceutical product development and popularization;
   w. F.D.A. involvement;
   x. Market characteristics;
   y. Generics v. brand names; and
   z. Stability of the marketplace;

In conducting the survey, I took into consideration the market, product availability, diversification and specialization. I looked at the topics from the standpoint of the manufacturer, the wholesaler and the retailer. I considered competition in the retail pharmaceutical industry,

price determination, advertising, detailing and other forms of promotion, as well as staffing, acquisition of businesses, brand image, detailing, promotion, regulations, publications, professional standards, attitudes, nature of drug store and retail pharmacy practices, such as independence, traditional goods, sales and discounts, consumer attitudes, competition, promotion and pharmacy ethical and professional responsibilities during the '50s and '60s. I also investigated and researched prescription habits, record keeping, product variation, wholesaler to retailer supply systems, trademark and generic names, hospital verses retail operations, stocking and dispensing practices and sales and sales record keeping.

Virtually the only body of information I did not have aecess to was the Lilly Digest, which was a compilation published annually by Eli Lilly during that period, which covered such topics as average volume, prescription charges, costs of goods sold, expenses, new prescriptions, refills and advertising at the retail level. I understand this research is included in the Lilly Digest, which the Company has been requested to open but has not seen fit to share with us.

My qualifications for this survey are:

I began my career in retail pharmacy in 1944, as a clerk and stock boy in my father's retail pharmacy, Sparr's Drug Store, Inc., which was across the street from the Boston Lying-In Hospital and adjacent to the Harvard Medical School and the Harvard School of Public Health. As you know, DES was popular in Massachusetts, as the Smith's and other promoters lived there through the Lilly detailmen, Jason Goldsmith and Harry Fine and Louis Bromberg.

From the age of 10 until I was 17, I was a stock boy, pharmacist's assistant and would unpack orders and stock the shelves from the drug wholesalers. In 1951 at the age of 17, I became a pharmacy student at Massachusetts College of Pharmacy and Health Sciences but continued to work in the store 20 or 30 hours a week as I had for the prior seven years. While in pharmacy school, I continued to work at the store part-time as an apprentice pharmacist from the years 1951 to 1955 and thereafter, engaged in the field of pharmacy continuously and exclusively until the present, except for two years of military service as a pharmacist. I hold a Bachelor of Science Degree in Pharmacy from the Massachusetts College of Pharmacy and I am registered in Massachusetts, New York and California. I hold a Masters in Health Care Management from Pacific Western University.

My employment in the field of pharmacy has given me the opportunity to observe the retail stocking of drugs primarily because of the store's proximity to the Boston Lying-In Hospital (where DES prescribing obstetricians were located), and therefore am conversant with the manner and method of prescription of DES in the 1950s and 1960s by those obstetricians in the Boston area who popularized this drug. Boston Lying-In Hospital was the main Obstetrics

hospital in Boston in the 1950s and 1960s as it was the Harvard teaching hospital where Smith and Smith popularized Stilbestrol for the use in preventing accidents of pregnancy.

During the 1950s and 1960s, I maintained close relationships with Lilly detailmen, and Gilman & McKesson wholesalers and actually and frequently ordered, stocked and dispensed DES. As a practicing pharmacist and active participant in pharmacy affairs, I was conversant with other pharmacists in the Boston area. At this time I had the opportunity to fill prescriptions for Stilbestrol and am familiar with the physician prescribing habits, pharmacy standard of care, usual and routine pharmaceutical brands dispensing and stocking.

Personal familiarity with DES stocking and Dispensing:

I am familiar with Diethylstilbestrol, also known as DES and Stilbestrol, as a hormone used in pregnancy. I filled on the average of three or four prescriptions a week for DES starting in the late 1950s, I have seen it on the shelves in many other pharmacies since 1951. I knew it was indicated for prevention of miscarriage, among other uses, and I knew it came in different strengths from .1 mg to 25 mg and in white uncoated tables as well as red-coated pills. Diethylstilbestrol was the only popular oral hormone medication given in the 1950s and 1960s to pregnant women. In the Boston area it was the drug of choice and the standard treatment for pregnant women and the only popular oral medication regularly used for this purpose. I am familiar with the Lilly publication "De Re Medica" that was sent to the physicians of America, which advocates DES as the best medication for avoiding miscarriage. I know that physicians in Massachusetts received this Lilly publication as well as P.D.R. and the other publications.

The consistency of DES marketing 1955 to 1971:

I have reviewed the commercial DES literature including PDR, Red Book, Blue Book, manufacturer brochures, and U.S. Pharmacopoeia from the 1950s and 1960s. I have also reviewed Lilly publications in general from the 1950s and 1960s, such as field reference manuals, product labeling, inserts, product brochures, Title and Till and other Lilly publications regarding competitive pharmaceutical manufacturers. I have reviewed a host of literature as set forth in Exhibit 6 and consulted additional texts set forth therein. I was familiar with this material in the 1950s, 1960s and 1970s. From these readings as well as my observations of the practice of pharmacy, I observed the changes occurring in the marketing, ordering, stocking and dispensing of retail pharmaceuticals over the last half century, with special focus on DES. These practices have remained relatively stable during the last 1950s and 1960s. In addition to those text and journals attached as Exhibit 6 and the Lilly publications attached as Exhibits 12, 13, 14 and 16, I have reviewed other documentation concerns with DES marketshare including:

1. Affidavit of Philip Cafferty a pharmacist and Lilly sales manager and detailman, Appendix 18.

2. The DES Matrix, as it evolved in the New York and California litigation. (Appendix 17).

3. The sworn Statement of John P. Della Volpe, an employee with the McKesson and Robins Company one of the largest Lilly wholesalers. (Appendix 20).

4. A dozen depositions of practicing pharmacists in this period on the question of brand identification.

I have reviewed the expected testimony of Lilly's expert's Keith Leffler, Raymond A. Gosselin, Benjamin P. Sachs, M.D. and Lynne Silvia (Appendix 5) and their conclusions that Lilly held 30 to 34% of the DES market for the pregnancy size DES which is without any basis for the following reasons:

1. Mr. Gosselin is dead; and
2. Dr. Sachs' study design is flawed.

I reviewed the following text regarding retail pharmacists.

1. Alreck and Settle, *The Survey Research Handbook*, 2nd Ed.;
2. Smith, in *Principles and Pharmacy Marketing*, Lea and Febiger, 1968;
3. Kremers and Urdang's, *History of Pharmacy*, 3rd Edition, 1963, Lippincott;
4. *The United States Pharmacopeias* for various years;
5. *Journal of the American Pharmaceutical Association* for various years;
6. *The Red Book, Blue Book and Pink Sheets* for various years;
7. *The American Professional Pharmacist*; and
8. *The American Druggist* for various years.

The Vanderschmidt Study, which lends support to my personal research and investigation (Appendix 9), was secured and distributed by an independent pharmacy consultant of high credentials. The questionnaire was processed anonymously; safeguards were employed to exclude any biases as set forth in your letter to me of May 5th. None of the responders knew or had any information of the parties involved, the purpose of the study, nor the injuries of your clients. I believe that the study was scientifically designed with data adequately secured and interpreted. Dr. Vanderschmidt's conclusions are:

1) The Survey is trustworthy and based on a well grounded sampling, considering the passage of time from the event we are considering.

2) Hearsay and memory risks were satisfactorily minimized.

3) The numbers of adequate responders was properly surveyed to obtain a representative sample.

4) The Questionnaire contained clear, precise and non-leading questions which were answered appropriately consistent with the sources of information.

5) The responders had no knowledge of the litigation nor could they have been influenced or sympathetic to any individual or company.

6) The mailings, returns and collating were protected, as well as the security and impartiality of the survey.

7) Statistical analysis was in accordance with accepted and standard epidemiological procedures.

8) Neither you nor anyone else engaged in such litigation nor any of the claimants have played any role in the design or conduct of this survey nor my conclusions.

Conclusions:

Based on my review of the literature, my experience, my discussions with other pharmacists and all the research and the investigation set forth above, it is my opinion to a reasonable degree of pharmaceutical and statistical certainty that Dr. Vanderschmidt's conclusion that Lilly's share of the DES market, in the pregnancy sizes, was 90% is conservative. From my standpoint, I would conclude that the following proportions are a more precise exact and realistic share of the market, as follows:

1. Lilly – 94%;
2. Squibb – 2%;
3. Assuming that the New York and California matrices are correct, Parke Davis, Brewer, Upjohn, Merck, Premo, and the other brands listed on these matrices, comprise the remaining 4% of the market.

Attached as Exhibit 19, is a listing of assorted synthetic estrogens or DES-like drugs on the market in the fifties and sixties. I understand there are some contentions made that DES

(Diethylstilbestrol) was not the only or not the most popular synthetic estrogen in use for prevention of the accidents of pregnancy.

In all the research above, the hundreds of pharmacists and doctors with whom this topic has been discussed was never any mention to any of the products listed on exhibit 19, other than DES (Diethylstilbestrol) in the Commonwealth of Massachusetts. I am familiar with DES but experienced that Stilbestrol was the only synthetic estrogen product prescribed or dispensed.

Additionally, I am informed that a contention has been made that there may have been non-Lilly brands of DES which were white and cross-scored. I have reviewed the P.D.R., Red and Blue Books and volumes of photographs of DES products. From my experience, personal familiarity with these products, a review of the literature, I can state with absolute certainty that the only popular DES product which appeared round, white and cross-scored, about the size of an aspirin without any other imprint or logo, as in Exhibit 11, was the Lilly DES 25_{mg} product.

I declare, under the penalty of perjury, that the foregoing statement is true and correct, based upon my personal knowledge of the facts set forth.

10/12/04
Date

Harold B. Sparr, R.PH., M.S.

WITNESS:

Appendix 5

A Phase II Study of a Combination of Pemetrexed and Gemcitabin in Patients with Metastic Breast Cancer: an NCCTG Study

Summary ID# 2245

Clinical Study Summary: Study H3E-MC-JMCF

A Phase II Study of a Combination of Pemetrexed and Gemcitabine in Patients With Metastatic Breast Cancer: an NCCTG Study

Date summary approved by Lilly: 27 January 2006

Brief Summary of Results

- This was a single-stage Phase 2, non-randomized, open label, uncontrolled study with an interim analysis conducted to assess the efficacy and toxicity of pemetrexed (Pem) in combination with gemcitabine (Gem) in outpatient services for patients with metastatic breast cancer.
- The primary objective of this study was to assess the efficacy and toxicity of pemetrexed in combination with gemcitabine in patients with metastatic breast cancer who have received an anthracycline and a taxane.
- Of the 59 patients evaluable for primary efficacy (Tumor response population), 14 (23.7%) partial responses were reported for an objective response rate of 23.7% (95% CI: 16 to 39%). The disease was stable in 9 (15.3%) patients for greater than 6 months with a median of 11.0 months (range: 6.7 to 36.6 months).
- The median survival time was 10.3 months (95% CI: 8.3 to 18.9 months) and the 1-year survival rate was 49% (95% CI: 38 to 64%).
- The median time to progression was estimated to be 3.7 months (95% CI: 2.3 to 5.3 months).
- One death was reported during the treatment because of study disease.

- Thirty-two percent of the patients required a dose reduction after Cycle 1. and approximately 30% of patients required a dose reduction in Cycles 4 to 8.
- The most common hematological Grade 3/4 toxicity for the combination of pemetrexed and gemcitabine was neutropenia occurring in 83% of patients (17% Grade 3 and 66% Grade 4). and leukopenia occurring in 29% of patients (19% Grade 3 and 10% Grade 4).
- Thrombocytopenia was also common occurring in 27% of patients (24% Grade 3 and 3% Grade 4).
- Fatigue (17%) and dyspnea (15%) were the most common nonhematological Grade 3 or 4 toxicities, followed by rash (7%), and anorexia (5%).
- No difference in Grade 3/4 toxicities was observed among patients with different pre-therapy homocysteine levels. Eighty-nine percent (40/45) of patients had homocysteine levels of less than 10 μM at baseline.

Title of Study: A Phase II Study of a Combination of Pemetrexed and Gemcitabine in Patients With Metastatic Breast Cancer	
Investigator(s): This multicenter study included 1 principal investigator.	
Study Center(s): This study was conducted at 12 study sites in one country. This trial was conducted through a network of cancer specialists at community clinics, hospitals and medical centers. Although there was only one PI from the research base, patients were enrolled by physicians across a number of sites.	
Length of Study: 38.6 months Date of first patient visit: 20 December 2000 Date of last patient visit: 9 March 2004	**Phase of Development:** II
Objectives: • The primary objective of this study was to assess the efficacy and toxicity of pemetrexed (Pem) in combination with gemcitabine (Gem) in patients with metastatic breast cancer who have received an anthracycline and a taxane. • The secondary objective was to describe the time to disease progression (TtPD) and the effect of treatment on overall survival (OS).	
Study Design: This was a single-stage Phase 2, non-randomized, open label, uncontrolled study with an interim analysis conducted to assess the efficacy and toxicity of Pem in combination with Gem in outpatient services for patients with metastatic breast cancer. Gemcitabine was given by intravenous (iv) infusion at a dose of 1250 mg/m^2 on Day 1 and Day 8 of a 21-day cycle. Pemetrexed was given by iv infusion at a dose of 500 mg/ m^2 after the end of gemcitabine infusion on Day 8 of a 21-day cycle. Observation for complete response (CR) patients were every 3 months for 1 year, then every 6 months until disease progression and then patients went to event monitoring phase. For patients with a partial response (PR) or had a stable disease (SD), treatment continued till progressive disease or unacceptable toxicity when patients went to the event-monitoring phase.	
Number of Patients: Planned: 55 patients Randomized/Enrolled: 59 Pem/Gem patients Completed: 59 Pem/Gem patients	

Diagnosis and Main Criteria for Inclusion: Patients were women 18 years or older with histologic or cytologic confirmed bi-dimensionally measurable breast cancer with clinical evidence of metastatic disease. Patients must have had an anthracycline and a taxane or a combination of both, in the adjuvant or metastatic setting with no more than 1 prior chemotherapy regimen for metastatic disease (unless these were a taxane and anthracycline).

Study Drug, Dose, and Mode of Administration:
Gemcitabine 1250 mg/m^2 was given intravenously (iv) over 30 minutes on Day 1 and Day 8 of a 21-day cycle.
Pemetrexed 500 mg/m^2/day, given iv over 10 minutes after the end of gemcitabine infusion on Day 8 of a 21-day cycle.
Folic acid 350 to 600 µg was given orally daily starting 7 days prior to the first dose of the study drugs. Folic acid was to continue daily until 3 weeks after the last dose of pemetrexed.
Vitamin B_{12} was administered as a 1000 µg intramuscularly injection starting 7 days prior to the first dose of pemetrexed and repeated every 9 weeks until 3 weeks after the patient discontinued from study therapy.
Dexamethasone (4 mg twice per day) or its equivalent was taken orally on the day before, day of, and day after all doses of pemetrexed.
Anti-emetics were given before chemotherapy on Days 1 and Day 8 according to institutional guidelines.

Duration of Treatment: Two additional cycles of Pem/Gem would be continued if a patient had achieved a complete response. For patients with a partial response (PR) or stable disease (SD), treatment with Pem/Gem continued until the time of progressive disease or unacceptable toxicity when patients went to the event-monitoring phase. In the event of unacceptable toxicity in the absence of an objective response or patient refusal/withdrawal, the patients went to the event-monitoring phase. Follow-up continued until death or 5 years. Further follow-up was not required if a patient was still alive after 5 years after registration.

Variables:
Efficacy: Efficacy measures included tumor overall response rate (CR or PR rate) as defined by Response Evaluation Criteria in Solid Tumors (RECIST), and time-to-event parameters: duration of response, survival time, 1 year survival rate, SD, TtPD, and OS.
Safety: Safety measures included physical examinations, clinical laboratory tests (hematology, blood chemistries, creatinine clearance), plasma homocysteine (Hcys) level at baseline and at Cycle 2, adverse events and number of blood transfusion required. All toxicities were graded according to the National Cancer Institute Common Toxicity Criteria.

Evaluation Methods:
Statistical: This single stage, non-randomized Phase 2 study with an interim analysis was based on optimal two-stage designs by Simon (1989). Fifty-nine patients were enrolled in this study to evaluate tumor response rate to pemetrexed in combination with gemcitabine. Radiologic studies (roentgenograms, computed axial tomographic scans or magnetic resonance imaging) were performed at baseline and after every two cycles of therapy to assess tumor response. A treatment success was defined as either a CR or PR observed on 2 consecutive evaluations at least 4 weeks apart. This study was designed to test the null hypothesis that the true treatment success rate is at most 0.15. The smallest treatment success proportion that would imply this regimen warrants further study was 0.30. The distribution of time to progression and survival time was estimated using Kaplan-Meier analysis. Confidence intervals for the true treatment success rate were constructed according to the method of Duffy and Santer.
Homocysteine Levels: Homocysteine (Hcys) is a sensitive biomarker for folate inadequacy and a significant risk factor for treatment-related toxicities. Fifty-six patients were included in the Hcys analysis at baseline. Twenty-seven patients were included in the Hcys at Cycle 2.

Results:

Patient Demographics

A total of 59 female patients (pts) were enrolled between December 2000 and January 2003. Table 1 displays the demographics and disease characteristics of these patients. The majority of patients were white (55 pts. 93.2%). Forty-six (78.0%) patients were post-menopausal and 51 (86.4%) patients had visceral metastasis. The number of prior adjuvant chemotherapy regimens was 0 (5 pts, 8.5%) or 1 (54 pts. 91.5%). The number of prior metastatic chemotherapy regimens was 0 (23 pts, 39.0%), 1 (35 pts, 59.3%), or 2 (1 pt, 1.7%). Twenty-eight (47.5%) patients had received prior hormonal therapy.

Table 1. Baseline Patient Demographics

Variable	N=59 n (%)
Median Age (range)	51 (32-74)
Age Group:	
<40	10 (17.0)
40-49	18 (30.5)
50-59	16 (27.1)
60-69	9 (15.3)
≥70	6 (10.2)
Race:	
Asian	1 (1.7)
Black	3 (5.1)
White	55 (93.2)
Performance Status:	
0	32 (54.2)
1	27 (45.8)
Dominant Disease Status:	
Soft tissue	8 (13.6)
Visceral	51 (86.4)
Bone	0 (0.0)
Menopausal Status:	
Pre-menopausal	13 (22.0)
Post-menopausal	46 (78.0)
Estrogen Status:	
Negative	26 (44.1)
Positive	32 (54.2)
Unknown	1 (1.7)
Progesterone Status:	
Negative	25 (42.4)
Positive	31 (52.5)
Unknown	3 (5.1)
# Prior Adjuvant Regimens:	
0	5 (8.5)
1	54 (91.5)
2	0 (0.0)
# Prior metastatic Regimens	
0	23 (39.0)
1	35 (59.3)
2	1 (1.7)
Prior Hormomal Therapy	28 (47.5)

Abbreviation: n = number of patients; N = Total number of enrolled patients.

Patient Disposition

Three hundred and sixty-two doses of treatment were administered throughout the study with a median of 5 cycles per patient (range 1 to 22). All 59 patients have discontinued study treatment. The most common reasons for discontinuing treatment include disease progression for 37 (63%) patients, adverse event for 9 (15%) patients, and patient refusal for 8 (14%) patients. One (3%) patient died during the study treatment. The indicated cause of death was due to disease progression. Figure 1 presents the disposition of all patients who enrolled into the study.

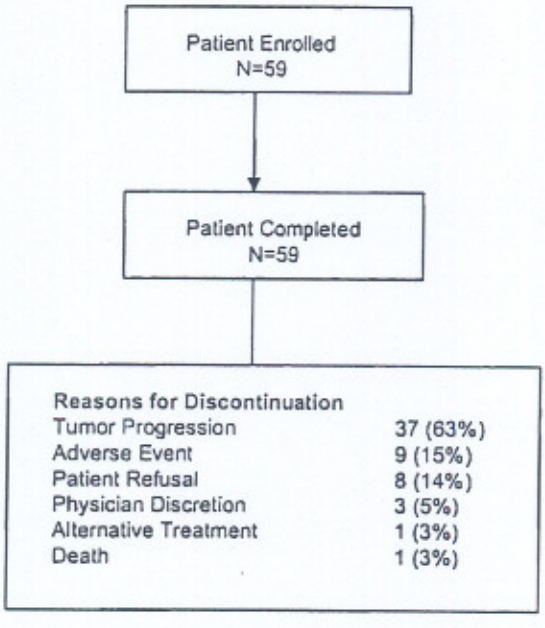


Figure 1. Patient disposition.

Primary Efficacy Endpoint

Table 2 presents the objective best response data. None of the patients (0%) had a complete response (CR). Fourteen (23.7%) patients had a partial response (PR). Table 3 summarizes the overall response rate. The disease was stable in 9 (15.3%: 95% CI: 5 to 32%) patients for greater than 6 months with a median of 11 months (range: 6.7 to 36.6 months.

Table 2. Objective Best Response

Best Confirmed Response	N=59 n (%)
CR	0 (0.0)
PR	14 (23.7)
SD	9 (15.3)

Abbreviation: CR = complete response; n = number of patients; N = total number of enrolled patients; PR = partial response; SD = stable disease.

Table 3. Summary of Overall Response Rate

	N=59
Overall response rate (CR + PR) (%)	23.7
95% CI for response rate	(16 to 39%)

Abbreviation: CI = confidence interval; CR = complete response: N = total number of enrolled patients; PR = partial response.

Secondary Efficacy Endpoints

Table 4 summarizes the secondary efficacy endpoints of duration of response, overall survival and time to disease progression. The median duration of response was 8.3 months (range 1.6 to 16.9 months). The median survival time was 10.3 months and the 1-year survival rate was 49% (95% CI: 38 to 64%). The median time to progression was estimated to be 3.7 months (95% CI: 2.3 to 5.3 months).

Table 4. Summary of Secondary Efficacy Endpoints

	mo	95% CI (mo)
Median duration of response	8.3	1.6 to 16.9
Median overall survival	10.3	8.3 to 18.9
Median time to disease progression	3.7	2.3 to 5.3

Abbreviations: CI = confidence interval: mo = months.

Figure 2 represents the Kaplan-Meier curves for overall survival and time to disease progression.

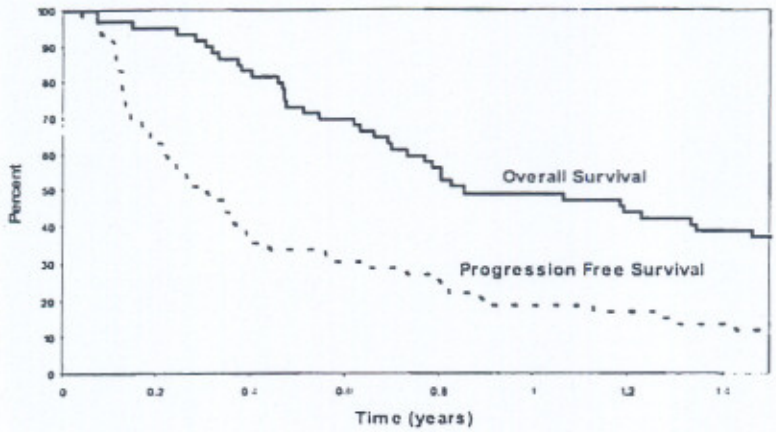


Figure 2. Kaplan-Meier curves for overall survival and time to disease progression.

Safety

Any adverse event (AE) considered at least possibly related to treatment was defined as a toxicity. Toxicity data were available for all patients. Table 5 displays the frequency and severity of the Grade 3 and 4 toxicities occurring in at least 5% of all patients. Neutropenia was the most common and severe hematological toxicity reported with 17% of patients had Grade 3 and 66% had Grade 4. Fatigue (17%) and dyspnea (15%) were most common for non-hematological Grade 3 and 4 toxicities, followed by rash (7%) and anorexia (5%).

Table 5. Common Grade 3 and 4 Toxicities Occurring in at least 5% of All Patients

Variables	Grade 3 (%)[a]	Grade 4 (%)[a]
Neutropenia	17	66
Leukopenia	19	10
Thrombocytopenia	24	3
Fatigue	14	3
Dyspnea	12	3
Febrile neutropenia	12	2
Rash	5	2
Anorexia	3	2

[a] Percentage of patients with adverse events at least possibly related to study treatment.

Table 6 represents complete dose information of study drug administered during the first 8 cycles of treatment. Approximately 25% of the patients received the full dose during Cycles 5 to 8. The median dose level administered was 500 mg/m^2 for pemetrexed and 1250 mg/m^2 for gemcitabine during Cycles 1 and 2. Thirty-two percent of the patients required a dose reduction after Cycle 1, and approximately 30% of patients required a dose reduction in Cycles 4 to 8.

Table 6. Study Drug Administered During the First Eight Cycles of Treatment

	Gemcitabine				Pemetrexed		
Cyc	No. of Pts on study drug	% Pts receiving full dose	% Pts receiving dose reduction during cycle	Median dose level administered (mg/m^2)	% Pts receiving full dose	% Pts receiving dose reduction during cycle	Median dose level administered (mg/m^2)
1	59	91.5	0.0	1250.0	96.6	0.0	500.0
2	53	58.5	32.1	1250.0	64.2	32.1	500.0
3	39	48.7	17.9	946.4	51.3	20.5	473.8
4	37	40.5	27.0	938.1	37.8	27.0	375.2
5	30	26.7	30.0	929.0	26.7	30.0	370.5
6	27	22.2	25.9	904.3	22.2	25.9	359.1
7	18	22.2	27.8	627.2	22.2	27.8	246.1
8	16	25.0	31.3	706.0	25.0	31.3	268.5

Abbreviations: Cyc = cycle; No = number; Pts = patients.

Homocysteine (Hcys) levels were available for 56 patients at baseline (pre-therapy) and for 27 patients at Cycle 2. There were no significant differences observed between the median Hcys levels at baseline 8 µM (range 3 to 17) and 8 µM (range 6 to 16) at Cycle 2. Table 7 presents baseline Hcys level and toxicity distribution analysis at 10 µM Hcys level cut-off point. Eighty-nine percent (40/45) of patients with a baseline Hcys level of <10 µM and 91% (10/11) of patients with a baseline Hcys levels >10 µM experienced a Grade 3 or Grade 4 hematological toxicity (p=0.85). Similarly. 58% (26/45) of patients with a baseline Hcys levels <10 µM and 64% (7/11) of the patients with a Hcys level >10 µM had a Grade 3 or Grade 4 non-hematological toxicity (p=0.72).

Table 7. Baseline Homocysteine Level and Toxicity Distribution

		Toxicity	
		Hematological Grade 3 or 4	Non-hematological Grade 3 or 4
Homocysteine level	N	n (%)	n (%)
≤10	45	40 (89)	26 (58)
>10	11	10 (91)	7 (64)
		(p=0.85)	(p=0.72)

Abbreviation: N = total numbers of patient; n = number of patients; p = p-value for difference.

Appendix 6

Selections from the Deposition of George W. Price, July 29, 1983

VOLUME I
PAGES 1-90
EXHIBITS Per Inde

STATE OF CALIFORNIA

San Francisco, ss

Superior Court
No. 768299

* * * * * * * * * * * * * * * * *
*
MARGARET LEE *
*
vs. *
*
ABBOTT LABORATORIES, ET AL *
*
* * * * * * * * * * * * * * * * *

DEPOSITION of GEORGE W. PRICE, a witness called on behalf of the Defendant, taken pursuant to Notice under the California Rules of Civil Procedure, before Lynn A. Leonard, a Registered Professional Reporter and Notary Public within and for the Commonwealth of Massachusetts, at the law offices of Rivkind, Baker & Golden, 25 Braintree Hill Park, Braintree, Massachusetts, on Friday, July 29, 1983, commencing at 10 a.m.

Q. You can answer the question.

A. Well, if I had a prescription for Stibestrol and I was going to fill it and there was no manufacturer stated on the original prescription by the doctor, I probably would have filled it with Lilly's. As far as what somebody else did, there is no way I could tell.

Q. Are you saying that in 1950 and '51, your drug of choice in that instance would have been Lilly, if there was no recommended manufacturer?

A. Yes.

Q. Do you know what Mr. Carnes' custom and practice at that time was in reference to Stibestrol?

A. No, I do not.

Q. Do you know what Mr. Duprey's custom and practice would have been in reference to Stibestrol?

A. No, I do not.

Q. Just clarify for me when Mr. Duprey was a pharmacist out at the Hingham Pharmacy, if you remember?

A. All I can do is guess that it was 1948

A. Yes.

Q. Living in Boson?

A. The last three years, yes.

Q. Would you have even been in the pharmacy during the week during February, 1950 or February or March, 1951?

A. Probably not.

Q. Is it your recollection that most of physicians in the Hingham area prescribed Stibestrol generically, that is, by simply prescribing Stibestrol or Diethylstibestrol as opposed to indicating a manufacturer or brand name?

MS. WILSON: I'm going to object as calling for speculation.

A. Yes.

MS. STRASSFELD: Objection.

MR. VALIM: What is your objection, counsel?

MS. STRASSFELD: You're saying, most of the physicians in Hingham?

MR. VALIM: I just wanted to hear what the grounds were. He didn't get a chance to see it.

MS. STRASSFELD: Speculation.

Q. At the time when you were in the Hingham Center Pharmacy and working as a pharmacist, were most of the prescriptions for Stibestrol you saw in the form of a generic prescription as I have just described?

A. Yes.

Q. If at that time the Hingham Center Pharmacy had more than one manufacturer of DES on their shelf, was there anything to prevent a pharmacist from choosing any one of those to fill the prescription that was written generically?

A. No.

Q. By the way, when you filled the prescription for an item such as DES, did the customer get a better price per tablet if there were more tablets in the prescription?

A. Most likely, yes.

Q. So that a prescription for 100 or 50 might be less per tablet than a prescription for 12 or 15 or 20?

A. Yes.

Q. So it's clear, was there a price

Appendix 7

Selections from the Deposition of Harold B. Sparr, R. Ph., M.S., December 7, 2004

VOLUME I
PAGES 1 - 237
EXHIBITS Per Index

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

----------x

NANCY A. BOHLIN, INDIVIDUALLY,
AND AS MOTHER AND NEXT FRIEND OF
SAMANTHA A. BOHLIN, A MINOR,
Plaintiff

v.

ELI LILLY AND COMPANY,
Defendant

Civil Action
No. 03-CV-11577
(MEL)

----------x

DEPOSITION OF HAROLD B. SPARR
Tuesday, December 7, 2004
Foley Hoag, LLP
155 Seaport Boulevard
Boston, Massachusetts

REPORTER: Virginia L. Barry, RPR/CSR

related to particular cases or investigations for a pharmacy; is that right?
A. Correct.
Q. And how did you find the individuals that you would interview independent of an investigation for a particular pharmacy or case?
A. They were people that I knew personally, and some of these people that I knew personally that gave me a statement suggested other people to me, and I would call them.
Q. Are there any other ways in which these people came to you?
A. I found some in the alumni book for Mass. College of Pharmacy.
Q. And for these -- I'm sorry, I didn't mean to cut you off. Are there any others besides the alumni book for Mass. College of Pharmacy, the people you knew personally, and people that your personal friends recommended to you?
A. And people that I met at various meetings --
Q. Okay.
A. -- throughout the country.
MR. LEVINE: Does this include people

you spoke to over the '50s and '60s, too?
THE WITNESS: Correct. Well, I spoke to a lot of people.
Q. Now, I'm going to -- maybe we'll find out who you spoke to. Now, when you did this, what was the purpose of your interviewing them and asking them about this if it wasn't for a particular case or a particular investigation?
A. It was to satisfy myself with what the product was.
Q. Anything else, any other reasons for doing this?
A. No.
Q. When were these investigations undertaken, were they after the time you were engaged by Mr. Levine in November of 2003?
A. Yes.
Q. When you mentioned meeting people at meetings, what meetings were you meeting people at?
A. I go to the annual National Association Boards of Pharmacy meeting. I go to the district meetings of the National Association of Boards of Pharmacy, and American Association of Colleges of Pharmacy. I go to the Massachusetts Pharmaceutical

Association Meetings. I go to the Massachusetts Independent Pharmacists Association meeting.
Q. I'm sorry, Independent?
A. Yes, MIPA.
Q. And what was the nature of the inquiry you made to these people that you met at these meetings?
A. I would ask them if they remembered dispensing diethylstilbestrol in the '50s and '60s.
Q. Yes, what else?
A. Some said yes, some said no.
Q. Yes, and what other questions would you ask?
A. I would then give them a statement and ask them to fill it out for me.
Q. Give them the statement in the blank form that we have now?
A. That is correct.
Q. Are there any other questions you asked them?
A. No.
Q. Did you do anything to confirm that, in fact, they had been practicing pharmacists dispensing DES in the '50s and '60s?
A. I would check their licenses on the Board

of Pharmacy Web site to see when they were initially licensed.
Q. And these would be for the Massachusetts people; is that correct?
A. That is correct.
Q. Is there anything else you would do besides check their date of registration?
A. No.
Q. Now, Mr. Sparr, when you would ask them about DES, did you ask them specifically about dosages of DES?
A. Yes.
Q. Now, the form doesn't ask specific dosages; does it?
A. No.
Q. So when you gave that to them, they were just asked to fill out about DES or diethylstilbestrol; is that correct?
A. Correct.
Q. Would you make any notes about any of the conversations that you had with these people about the dosages that they had?
A. At meetings?
Q. Yes.

Appendix 8

Eli Lilly Wholesaler Agreement

1969-1970

ELI LILLY AND COMPANY

Warehousing and Distribution Service Agreement

This Agreement, when executed by the Wholesaler's authorized representative and returned to, and executed by, Eli Lilly and Company (hereinafter called "Lilly") at Indianapolis, Indiana, will state the terms and conditions of the Wholesaler's Lilly franchise for the period indicated herein.

I. **The Wholesaler Agrees:**

A. **Inventories.**

1. To purchase from Lilly and maintain at all times a complete inventory of the Lilly Products listed in the Lilly Price List (such products hereinafter called separately and collectively "Products") sufficient to supply demand, and to resort to drop-shipment orders only when necessary because of conditions beyond the Wholesaler's control.
2. To maintain the Products under proper storage conditions, including such refrigeration as may be specified by Lilly.
3. To supply only Products that are not out-of-date, damaged, or shopworn.

B. **Sales Organization.** To maintain a sales organization, including outside salesmen, adequate for personal solicitation of orders for Products in Wholesaler's trading area.

C. **Sales Effort.** To promote the Products, to give them full selling efforts and full distribution services, and not to—

1. Refuse or fail to supply promptly the Products when specified, or
2. Give preference to any other brand of products when no brand is specified.

D. **Financial Statement.** To furnish Lilly upon request a copy of its annual financial statement or other evidence of its financial condition.

E. **Automatic Shipments.** To accept automatic shipment of Products in reasonable quantities.

F. **Payment for Products.** To pay in full all invoices for Products within sixty (60) days from the date thereof.

II. **Lilly Agrees:**

A. **Shipment to Wholesaler.** To sell and ship Products (other than Products restricted to sale on a third-party basis) to the Wholesaler at the Net Wholesale prices shown in the Pricers' Edition of the Lilly Price List in effect on the date of shipment, such Net Wholesale prices being equal to the Suggested Net Trade prices specified in the Pricers' Edition of the Lilly Price List less the following discounts:

1. Group I Products—(marked "I" in the Pricers' Edition of the Lilly Price List): 16⅔%
2. Group II Products—(marked "II" in the Pricers' Edition of the Lilly Price List): 20%

B. **Special Suggested Net Trade Prices.** To adjust the net wholesale prices on Products sold and shipped from the Wholesaler's inventory on transactions for which Lilly has recommended special suggested net trade prices. The adjustments shall be made in accordance with the procedure outlined in the Lilly Chargeback Manual. Chargebacks must be properly certified and submitted to Lilly at Indianapolis, Indiana, not later than the end of the month next following the month in which the sale is made by the Wholesaler. The adjustments will result in net wholesale prices which are equal to the recommended special suggested net trade prices less the following discounts:

1. **Sales at Special Suggested Net Trade Prices (e.g., from Quotations, Quantity Price Schedule, Purchase Agreements, etc.).**
   a. Total value (of each item in the case of single items or of all items in an assortment) of less than $50—

      Group I Products—16⅔%

      Group II Products—20%

   b. Total value (of each item in the case of single items or of all items in an assortment) of $50 or more—10%

2. **Sales on Special Offers (Identified as Such by Lilly).**

   a. Special Offers with a total value of less than $50—
   Group I Products—16⅔%
   Group II Products—20%

   b. Special Offers with a total value of $50 or more—10%
   except that in no event shall the total annual dollar volume (at special suggested net trade prices) of sales to all Wholesalers on Special Offers providing Wholesalers a 10% discount exceed 10% of the dollar volume (at suggested net trade prices) of Lilly's total domestic sales to all Wholesalers during the previous calendar year.

   (Note: "Total value" for the purpose of subparagraphs 1. and 2. of this Paragraph B. shall be calculated on the basis of the recommended special suggested net trade prices.)

C. **Shipment to Third Parties.** To sell the Products to the Wholesaler upon third-party orders with shipment direct to the customer (i.e., drop shipments) at the applicable suggested net trade prices, regular or special, less 10%.

D. **Transportation.** To ship the Products F.O.B. Indianapolis, Indiana, transportation prepaid, subject to the following:

1. **Transportation Selected by Lilly.** Lilly will prepay that portion of the transportation charges set forth below when routing is selected by Lilly.

   a. **Shipments to the Wholesaler:**

   (1) Special Shipments. All shipments of (a) Products deferred from previous orders; (b) Products that are newly released for Wholesaler stocks (initial shipment and all reorders for first thirty [30] days after release date); and (c) allocated shipments: 100%

   (2) Regular Shipments. Shipments, other than Special Shipments, covered by the first two orders each week marked "Transportation Prepaid" by the Wholesaler: 100%

   (Note: The "first two orders each week" means the first and second orders marked "Transportation Prepaid" received by Lilly at Indianapolis, Indiana, from the Wholesaler during the period beginning at the close of business Friday and ending the following Friday at the close of business, determined on the basis of the date and time stamp placed on the order by Lilly at the time of receipt. An order for purposes of the foregoing shall include all Products in an order received by Lilly at one time and for prompt shipment, even though for the purpose of handling and shipping it is necessary for Lilly to divide it into components, e.g., biologicals, narcotics, etc.)

   (3) All other shipments to the Wholesaler: None

   b. **Shipments on Third-Party Orders:**

   (1) Products not released for Wholesaler stocks: 100%

   (2) All other Products: 50%

2. **Transportation Selected by Wholesaler.** If the Wholesaler requests special routing of a shipment which results in a higher transportation cost than would be incurred as a result of the routing of Lilly's selection, then the extra cost shall be added to the invoice.

3. **Title and Risk of Loss.** Title and risk of loss shall pass to the Wholesaler when the Products are duly delivered to the carrier.

E. **Return for Credit.** To receive from the Wholesaler for credit the Products purchased from Lilly, subject to the following:

1. All returns must be sent to Lilly at Indianapolis, Indiana, accompanied by a Merchandise Returned Form (60 DQ 9408) signed by the Lilly salesman responsible for the Wholesaler. Transportation for returns made upon request by Lilly shall be paid by Lilly. Transportation for all other returns shall be paid by the Wholesaler. Full credit will be allowed at the Net Wholesale prices in effect on the date of the return, except on Products damaged while in the Wholesaler's possession.

2. Undamaged Products in original containers may be returned, except biological Products prior to their date of expiration and Products marked "Nonreturnable." No credit will be allowed for parts of sales packages, and any that are returned will be destroyed.

3. Damaged Products for which a claim can be substantiated against a carrier may be returned when sent to Lilly at Indianapolis, Indiana, free astray via responsible carrier.

4. Products damaged in shipment, but for which claim cannot be substantiated against a carrier because the concealed damage was not discovered within the required period for inspection, may be returned, subject to inspection and approval by the Lilly salesman responsible for the Wholesaler. Return shipment is to be made apart from regular returned goods shipments.

5. Actual salvage value, if any, will be allowed on Products damaged while in the Wholesaler's possession except that no allowance will be made in case of damage by careless handling or from such perils as are normally insured under the standard fire insurance policy, including extended coverage, vandalism, and malicious mischief.

III. **General Provisions.**

A. **Orders for Products.**

1. All orders are subject to acceptance and approval by Lilly at Indianapolis, Indiana. In the event of a shortage of any of the Products, Lilly shall have the right, in its sole discretion, to allocate such Products among its various wholesalers.
2. Lilly may, from time to time upon written notice to the Wholesaler, change the Group designation of any of the Products and may add or withdraw Products from the Pricers' Edition of the Lilly Price List, the regular Price List, and the Quantity Price Schedule.
3. Lilly may, in its discretion, designate certain Products which will be supplied in shelf-carton or shipping-case quantities only.

B. **Billing and Payment.**

1. Subject to the provisions of Section III. B. 2., all orders for Products shall be invoiced as of the day shipped at regular terms, i.e., sixty (60) days net, with 2 percent cash discount if remittances covering month-end statements in full are received by Lilly at Indianapolis, Indiana, on or before the fifteenth (15th) of the month immediately following. Month-end statements will include all invoices covering shipments made and all credits issued by Lilly during that month. Lilly may, at its option, grant extended dating on invoices covering initial distribution of selected new Products. Such extended dating, if granted, will be announced at the time of the initial shipment of the new Products.
2. Lilly may require that each order from the Wholesaler be accompanied by a certified check or other payment satisfactory to Lilly in an amount sufficient to cover the order less a cash discount of 2 percent in the event (a) reasonable grounds for insecurity arise with respect to the performance by the Wholesaler under this Agreement or (b) Lilly has given notice of termination of this Agreement.
3. Products shipped but not paid for at the time of the cancellation or termination of this Agreement shall be paid for in accordance with the terms of this Agreement.

C. **Inspection of Inventory.** A Lilly representative will consult with and advise the Wholesaler concerning the Wholesaler's inventory of Products and may inspect the same at all reasonable times.

D. **No Exclusive Territory.** This Agreement does not grant the Wholesaler any exclusive rights in any territory.

E. **Buyer-Seller Relationship.** The relationship created by this Agreement is a buyer-seller relationship and not an agency relationship.

F. **Change in Ownership of or Controlling Interest in Wholesaler.** The Wholesaler shall give ten (10) days' prior notice of the sale or other transfer of substantially all the assets of or a controlling interest in the Wholesaler.

G. **Direct Sales.** Lilly reserves the right to sell directly to the U. S. Government, the American Red Cross, and manufacturers.

H. **Repurchase of Stock.** Upon cancellation or termination of this Agreement, by expiration or otherwise, Lilly shall have the option to repurchase the Wholesaler's salable stock of Products at the Net Wholesale prices then in effect.

I. **Assignment of Agreement.** This Agreement may not be assigned by the Wholesaler without the prior written consent of Lilly.

J. **Contingencies Affecting Performance.** Neither party shall be liable for delay in performance or nonperformance caused by fire, flood, storm, earthquake, or other act of God, war, rebellion, riot, failure of carriers to furnish transportation, strikes, lockouts or other labor disturbances, act of governmental authority, inability to obtain material or equipment, or any other cause of like or different nature beyond the control of such party.

K. **Notices.** All notices under this Agreement shall be in writing and shall be considered given when delivered or mailed postage prepaid by registered or certified mail to the address of the party to whom notice is given as set forth on the next page.

L. **Termination or Cancellation.**

1. This Agreement shall terminate on June 30, 1970, unless renewed or sooner terminated as herein provided.
2. During its term this Agreement may be terminated by either party upon thirty (30) days' notice.
3. This Agreement shall terminate at the time substantially all the assets of or a controlling interest in the Wholesaler is sold or otherwise transferred to a new owner.
4. Either party may cancel this Agreement upon notice for breach by the other party of any covenant contained herein.

M. **Renewal.** At the option of Lilly and the Wholesaler, this Agreement may be renewed for successive terms of one (1) year. If the Wholesaler desires to renew, it shall send to Lilly at Indianapolis, Indiana, a written request for renewal forms before April 30. Duplicate copies of the renewal form executed by the Wholesaler shall be delivered or mailed to Lilly at Indianapolis, Indiana, not less than thirty (30) days before the expiration of any current term. If Lilly agrees to the renewal, it shall execute each renewal form and return one executed form to the Wholesaler.

N. **Entire Agreement.** This Agreement shall (1) supersede all prior contracts, agreements, and understandings between the Wholesaler and Lilly, all of which are hereby terminated, except any unexpired agency agreements between Lilly and the Wholesaler under U. S. Government contracts; (2) constitute the complete agreement of the parties; and (3) be controlling to the exclusion of all terms and conditions of the Wholesaler's purchase orders or other documents in conflict with this Agreement.

O. **Governing Law.** This Agreement shall be interpreted in accordance with, and governed by, the laws of the State of Indiana.

IN WITNESS WHEREOF, the Wholesaler has executed this Agreement and the same has become finally effective on the.....day of....., upon execution at Indianapolis, Indiana, by an authorized representative of Lilly.

WHOLESALER:

.....
(NAME)

.....
(STREET)

.....
(CITY) (STATE) (ZIP CODE)

.....
(*ESTABLISHMENT REGISTRATION NUMBER)

By.....
(SIGNATURE)

.....
(TITLE)

LILLY:

ELI LILLY AND COMPANY
307 East McCarty Street
Indianapolis, Indiana 46206

By.....
(VICE-PRESIDENT)

*Number assigned by the Food and Drug Administration to the facility covered by this Agreement.